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ONE YEAR DEADLINE FOR ONE ROOM SURGICAL PRACTICES IN NEW JERSEY

By: Jason J. Krisza, Esq., Alyson M Leone, Esq., and Grace D. Mack, Esq.

On January 15, 2018, Governor Christie signed S278(3R) into law. A previous version was pocket vetoed by the Governor in 2012. The law requires registered "surgical practices" or "one room" centers to be licensed by the New Jersey Department of Health ("DOH"). These centers were previously exempt from licensure and merely had to be registered with the DOH and remained under the jurisdiction of the New Jersey Board of Medical Examiners. Prior to the new law, ownership in these exempt one room centers was limited to physicians. Below is a summary of the "one room law."

I. Licensure of Surgical Practices within One Year

The new law requires all registered surgical practices in New Jersey to apply for licensure as an ambulatory care facility with the DOH within one year of the passage of the new law. NJSA 26:2H-12(g)(4).

II. Exemption from License and Ambulatory Assessment Fees

Surgical practices are exempt from the initial licensure fee and ambulatory assessment fees that apply to other licensed ambulatory care facilities. NJSA 26:2H-12(b). This exemption, however, does not apply to facilities that increase the number of operating rooms to more than one. NJSA 26:2H-12(g)(4).

III. Exemption from Physical Plant and Functional Requirements

The law creates certain exemptions from the physical plant and functional requirements to which other licensed ambulatory care facilities are subject. NJSA 26:2H-12(g)(4). The exemption only applies to certain classes of facilities:

a. CMS Certified

i. A surgical practice certified by CMS is not required to meet the physical plant and functional requirements specified in N.J.A.C. 8:43A-19.1 et seq.

b. AAASF or CMS Recognized Currently Operating

i. A surgical practice that is in operation on the date of enactment of the bill that is accredited by the American Association of Ambulatory Surgery

Facilities or any accrediting body recognized by CMS is not required to meet the physical plant and functional requirements specified in N.J.A.C. 8:43A-19.1 et seq.

c. Not Currently Operating and Not CMS Certified

i. Must meet physical plant and functional requirements specified in N.J.A.C. 8:43A-19.1 et seq.

ii. May apply for a waiver which will be granted by the Commissioner if it will not endanger the life, safety, or health of the patients or the public

IV. Scope of Services

Previous language granted a licensure exception to facilities that, among other things, did not expand the "scope of services" of the facility. The modified language deletes the scope of services language and replaces it with language with respect to the number of operating rooms, subject to the criteria set forth in NJSA 26:2H-12(g)(6).

V. Combinations

The law permits owners of surgical practices and ambulatory care facilities to combine so long as certain criteria are met, including that the combined facility cannot have more operating rooms than the previous facilities had in total. NJSA 26:2H-12(i)(7).

VI. Opportunities

The law offers opportunities for existing one room centers. It also offers opportunities to existing licensed facilities wishing to combine with an existing one room center.

VII. Licensure Process

It is important for registered one room centers to apply for licensure within the one year deadline. The DOH held training sessions for existing registered centers in early May to assist with the licensure process as well as the inspection process. Our health law team attended these sessions and will continue to monitor the process.

NEW JERSEY HEALTH CARE PROVIDERS BEWARE: NO MORE MUGS, PENS OR NOTE PADS! HOW THE NJ ATTORNEY GENERAL'S NEW RULES LIMITING ACCEPTANCE OF COMPENSATION FROM PHARMACEUTICAL COMPANIES MAY AFFECT YOU.

By: Jason J. Krisza, Esq. and Grace D. Mack, Esq.

On January 16, 2018, the New Jersey Attorney General adopted new rules governing the amount of influence pharmaceutical companies may have over prescribers through compensation arrangements. These rules are set forth at N.J.A.C. 13:45J (the "New Rules"). This article answers several questions that health care professionals may have in light of the adoption of the New Rules.

Who is subject to the New Rules?

The rules apply to "prescribers" which are defined as physicians, podiatrists, physician assistants, advanced practice nurses, dentists, or optometrists.[1]

What if I am receiving benefits from someone other than the pharmaceutical manufacturer?

The New Rules apply not only to pharmaceutical manufacturers, but also to their agents.

Can I receive gifts from a manufacturer or their agent?

You cannot accept anything of value from a pharmaceutical company or its agent even if it is nominal in value, unless it has the legitimate and sole purpose of being used in the prescriber's office.[2] This prohibition includes small items such as pens, note pads, clipboards, mugs or any other promotional item with the manufacturer's branding or logo.

What do the New Rules allow prescribers to accept from a pharmaceutical manufacturer or their agent?

Prescribers may accept the following items: 1. Educational items for use in the prescriber's office, e.g., anatomical models; 2. Subsidized registration fee at an education event provided the fee is available to all participants; 3. Meals (below $15.00/person) provided through an event organizer at an education event; 4. Meals (below $15.00/person) provided by a manufacturer; 5. Fair market value compensation for providing bona fide services as a speaker or faculty organizer or academic program consultant for an education event including travel, lodging, and other personal expenses; 6. Fair market value compensation for providing bona fide services as a speaker or faculty organizer or academic program consultant for promotional activity including travel, lodging, and other personal expenses; 7. Fair market value compensation for participating on advisory bodies under consulting arrangements including travel, lodging, and other personal expenses; 8. Reasonable payment or remuneration to prospective applicants for travel, lodging, and other personal expenses associated with employment recruitment; and 9. Royalties and licensing fees for use or purchase of a legally recognized discovery, e.g., use of a patent.[3]

Is there a cap on compensation for services?

Yes, there is a $10,000 cap per calendar year on compensation for services of presentation as speakers at promotional activities, participation on advisory boards, and consulting arrangements.[4] This cap does not apply to payments received for speaking at education events; however, all such expenses must be fair market value and set forth in writing.[5] A prescriber may also receive reasonable payment and remuneration for travel, lodging, and other personal expenses associated with such services.[6] The cap is an aggregate cap, meaning compensation from multiple manufacturers are aggregated together.[7] For example, if Manufacturer A provides you with $8,000 to speak at a promotional event, and Manufacturer B provides you with $3,000 to speak at another promotional event during that same calendar year, accepting the compensation from Manufacturer B will put you over the $10,000 cap.

What is an education event?

An education event is an event where: 1. The gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and 2. The main purpose for bringing attendees together is to further their knowledge on the topic(s) being presented.[8]

Am I allowed to accept an electronic device if I am using it for patient use?

Yes, provided that it is used by patients and remains in a common area of the prescriber's office.[9]

Can I accept sample medications?

Yes, provided they are to be used exclusively for the benefit of the prescriber's patients and the prescriber does not charge patients for such samples.[10]

Do I need to enter into written contracts with manufacturers before providing services on their behalf?

Yes, these arrangements must be in writing to meet the bona fide services exception to the New Rules.[11]

What about contracts that were entered into before the New Rules were adopted?

The New Rules do not apply to contracts entered into before January 15, 2018.[12] The applicable licensing board's regulations as well as federal law, which existed prior to the adoption of the New Rules and continue to exist, however, still apply to such relationships.

Do I need to disclose anything before making a presentation?

Yes, if you accepted payment for services from the sponsoring manufacturer within the last five years, you are required, either orally or in writing, at the beginning of the presentation to advise that you have accepted payment.[13] The New Rules do not require you to disclose the amount.

Conclusion

The New Rules limit the exceptions contained in the previous regulations. It is crucial that New Jersey physicians, podiatrists, physician assistants, advanced practice nurses, dentists, and optometrists review any potential arrangements with pharmaceutical manufacturers that may be implicated by the New Rules.

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[1] N.J.A.C. 13:45J-1.2. [2] N.J.A.C. 13:45J-1.3. [3] N.J.A.C. 13:45J-1.4. [4] N.J.A.C. 13:45J-1.6. [5] Id. [6] N.J.A.C. 13:45J-1.4(a)5,6. [7] N.J.A.C. 13:45J-1.6. [8] N.J.A.C. 13:45J-1.2. [9] N.J.A.C. 13:45J-1.4(a)1. [10] N.J.A.C. 13:45J-1.5 [11] N.J.A.C. 13:45J-1.2. [12] N.J.A.C. 13:45J-1.1A. [13] N.J.A.C. 13:45J-1.7.

NJ HUMAN TRAFFICKING PREVENTION, PROTECTION AND TREATMENT ACT ("NJ HUMAN TRAFFICKING LAW")

By: Grace D. Mack, Esq.

I. THE LAW: NJSA 2C:13-12 Training courses on handling, response procedures, investigation, prosecution of human trafficking cases

As part of the NJ Human Trafficking Law, the Department of Health (the "Department"), in consultation with the Commission on Human Trafficking (the "Commission"), requires "facilities" licensed by the Department to provide training on the handling of and response procedures to suspected human trafficking activities for employees, including licensed professionals. The NJ Human Trafficking Law provides that the Department shall define by regulation which employees are required, as a condition of their employment, to attend the training course. Verifiable completion of the training course by required employees is now a condition of issuance, maintenance, or renewal of any license, permit, certificate, or approval required, permitted to be granted, or issued to licensed health care facilities. The training course must be reviewed at least every two years and modified by the Department from time to time as need may require.

The Department's regulations, which are summarized below, contain a broad definition of employees who must receive training which includes all "workers" (regardless of the compensation arrangement, contractual status, or privilege status that may exist between the professional and the facility) who have direct contact and/or interaction with facility patients and/or visitors of facility patients, regardless of whether the contact or interaction is clinical or non-clinical in nature.

II. THE REGULATIONS: NJAC 8:43E-14.1 et seq.

A. 8:43E-14.2 Facility personnel to receive training (effective September 18, 2017)

A facility shall require workers who have direct contact and/or interaction with facility patients and/or visitors of facility patients to receive training, regardless of whether the contact or interaction is clinical or non-clinical in nature.

Workers include:

1. Health care professionals who hold professional credentials issued by the State of New Jersey, regardless of the compensation arrangement, contractual status, or privilege status that may exist between the professional and the facility, such as:
    i. Health care professionals whose professional practice is regulated pursuant to Title 45 of NJ law;
    ii. Licensed radiologic technologists;
    iii. Emergency medical technicians and paramedics;
    iv. Licensed nursing home administrators;
    v. Certified nurse aides;
    vi. Certified assisted living administrators; and
    vii. Certified personal care assistants and medication aides; and
2. Paid and volunteer facility workers.

Alternative Training:

As an alternative to a facility requiring workers to receive training from the facility, a facility can confirm that a worker already received that training from another entity, if the other entity is either:

1. A facility; or
2. A contractor or vendor that:
    i. Is under a contractual duty of honesty, good faith, and fair dealing to the facility; and
    ii. Maintains contemporaneous training records consistent with N.J.A.C. 8:43E-14.4 that are available upon request to the Department.

As a result, the requirements will be satisfied if a physician or other worker receives training at a hospital or other facility provided the alternative training is documented as provided in the regulations.

B. 8:43E-14.3 Required Training

Timing of Training:

A facility shall ensure that workers receive training:

1. By March 18, 2018, with respect to existing facility workers; and
2. Within six months of the first day of employment at the facility, with respect to persons who become workers at the facility after September 18, 2017.

Type of Training:

A facility shall require workers to receive training by means of one of the following:

1. The online webinar entitled “Recognizing and Responding to Human Trafficking in a Healthcare Context,” published February 2016 by the National Human Trafficking Resource Center (NHTRC), as amended and

supplemented, which is accessible:
i. Directly from the NHTRC website; and
ii. Through the website of the New Jersey Hospital Association; or

The online or in-person training entitled, "Stop. Observe. Ask. Respond to Human Trafficking (SOAR): A Training for Health Care and Social Service Providers," published August 2016, by the United States Department of Health and Human Services, as amended and supplemented;
i. Registration for the SOAR training is available through the website of the Office on Trafficking in Persons of the Administration for Children and Families of the United States Department of Health and Human Services, at http://www.acf.hhs.gov/endtrafficking/initiatives/soar;
ii. Participants who successfully complete SOAR training may apply for continuing education and continuing medical education credits from the SOAR training provider.

C. 8:43E-14.5 Policies and Procedures

A facility shall establish and implement written policies and procedures that address, at minimum, how the facility will:

1. Identify both clinical and nonclinical workers who, by virtue of their positions, have, or are likely to have, direct contact and/or interaction with facility patients and/or the visitors of facility patients, and are to receive training;
i. The Department encourages facilities to construe broadly the scope of workers who should receive training to facilitate the greatest possible opportunity for workers to develop awareness of, observe, and respond to, indicators of potential human trafficking;

Ensure that workers receive training; and
Maintain training records (see below).

D. 8:43E-14.4 Recordkeeping

A facility shall establish, maintain, and make available upon request of the Department, a record that identifies:

1. The name and position of each of the facility's workers required to receive training;
2. The date by which each worker is to receive training; and
3. The date on which the worker actually receives the training.
i. A facility shall note that the date on which a worker receives training in each worker's personnel record.

III. THE PENALTIES: NJAC 8:43E–3.4 (a) (21) Civil Monetary Penalties

Under the NJ Human Trafficking Law, verifiable completion of the training course by the required workers is now a condition of issuance, maintenance, or renewal of any license, permit, certificate, or approval required, permitted to be granted, or issued to licensed health care facilities. In addition, new regulations provide that the Department may assess a penalty against a licensed facility for violation of the licensure rules as follows:

1. For violations of N.J.A.C. 8:43E-14, governing human trafficking handling and response training, $1,000 per violation, which may be assessed for each day noncompliance is found.
2. Except for violations deemed to be immediate and serious threats, the Department may decrease the penalty assessed, based on the compliance history of the facility; the number, frequency and/or severity of violations by the facility; the measures taken by the facility to mitigate the effects of the current violation, or to prevent future violations; the deterrent effect of the penalty; and/or other specific circumstances of the facility or the violation.

UNDERSTANDING THE NEW JERSEY TELEMEDICINE LAW: 10 KEY ELEMENTS

By: Grace D. Mack, Esq. and Michael F. Schaff, Esq.

The New Jersey Telemedicine Law (Senate Bill Nos. 291, 652 and 1954) was enacted on July 21, 2017. The new law governs how telemedicine must be practiced in New Jersey and how providers will be compensated for the provision of telemedicine services.

"Telemedicine" is defined broadly under the new law as the delivery of a healthcare service using electronic communications, information technology, or other electronic or technological means to bridge the gap between a healthcare provider who is located at a distant site and a patient who is located at an originating site. "Telemedicine" does not include audio-only telephone conversation, electronic mail, instant messaging, phone text, or facsimile transmission. "Telehealth" is defined as the use of information and communications technologies, including telephones, remote patient monitoring devices, or other electronic means, to support clinical healthcare, provider consultation, patient and professional health-related education, public health, health administration, and other services.

The following is a summary of 10 key elements of the New Jersey Telemedicine Law ("the Law").

1. Who is subject to the Law?

The Law provides that any healthcare provider who uses telemedicine or engages in telehealth while providing healthcare services to a patient shall be subject to New Jersey jurisdiction if either the patient or the provider is located in New Jersey at the time services are provided.

2. Does the Law require coverage and reimbursement for telemedicine services in New Jersey?

Although the final version of the law contains parity provisions, it does not require "payment" parity. That is, the law does not require payors to compensate providers at the same rate whether an appointment is conducted remotely or face-to-face. The law does require that the payors subject to the Law provide coverage and payment for services provided through telemedicine and telehealth on the same basis that is applicable when the services are delivered in-person in New Jersey.

3. Does the Law apply to all health plans in New Jersey?

The Law applies to health plans offered by (i) carriers that offer a health benefits plan in New Jersey, (ii) State Medicaid and NJ FamilyCare programs, and (iii) the State Health Benefits and School Employees' Health Benefits Commission.

4. What actions must be taken during a telemedicine encounter in New Jersey?

Under the Law, a valid provider-patient relationship may be established via a telemedicine or telehealth encounter without an in-person exam. The Law requires certain actions be taken during a patient telemedicine encounter. A valid provider-patient relationship must include: properly identifying the patient using, at a minimum, the patient's name, date of birth, phone number, and address.

The identity, professional credentials, and contact information of a healthcare provider providing telemedicine or telehealth services shall be made available to the patient during and after the provision of services.

The contact information shall enable the patient to contact the healthcare provider, or a substitute healthcare

provider authorized to act on behalf of the provider who provided services, for at least 72 hours following the provision of services.

5. Are there any exceptions to the telemedicine provider-patient encounter requirements?

The Law provides that under certain limited circumstances telemedicine may be practiced without establishing a proper provider-patient relationship. These include:

- informal consultations without compensation;
- during episodic consultations by a medical specialist located in another jurisdiction;
- when a provider furnishes medical assistance in response to an emergency or disaster, provided that there is no charge for the medical assistance; and
- when a substitute provider acting on behalf of an absent provider in the same specialty provides services on an on-call or cross-coverage basis, provided that the absent healthcare provider has designated the substitute provider as an on-call provider or cross-coverage service provider.

6. What are the medical records requirements for telemedicine visits?

For an initial encounter with the patient, the provider shall review the patient's medical history and medical records prior to initiating contact with the patient.

In the case of a subsequent encounter, the provider may review the information prior to or contemporaneously with the telemedicine or telehealth encounter.

Following the provision of services using telemedicine or telehealth, the patient's medical information shall be made available to the patient upon request, and, with the patient's affirmative consent, forwarded directly to the patient's primary care provider or healthcare provider of record, or, upon request by the patient, to other healthcare providers.

7. Does the Law allow providers to prescribe medication during a telemedicine visit?

The issuance of a prescription based on a telemedicine or telehealth encounter shall be held to the same standard of care or practice standards as are applicable to in-person settings. Unless the provider has established a proper provider-patient relationship with the patient, a provider shall not issue a prescription to a patient based solely on the responses provided in an online questionnaire.

In most cases, the prescription of Schedule II controlled dangerous substances through the use of telemedicine or telehealth shall be authorized only after an initial in-person examination of the patient, and a subsequent in-person visit with the patient shall be required every three months.

Providers must also comply with federal law affecting remote prescribing, including the Federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008. Unless an exception applies, the Ryan Haight Act restricts prescribing controlled dangerous substances unless there is a prior in-person exam. New rules under the Ryan Haight Act to address advances in telemedicine are currently being considered by the DEA.

8. Does the Law limit the practice of telemedicine in New Jersey to doctors?

The Law does not limit the practice of telemedicine to medical doctors. Telemedicine may be provided in New Jersey by licensed:

- physicians, physician assistants;

- nurses, nurse practitioners;
- psychologists, psychiatrists, psychoanalysts, clinical social workers, professional counselors;
- respiratory therapists, speech pathologists, audiologists, optometrists;
- or any other healthcare professional acting within the scope of a valid license or certification issued pursuant to Title 45 of NJ law.

9. Are there any reporting requirements for the practice of telemedicine in New Jersey?

There is an annual registration requirement under the Law. Each telemedicine or telehealth organization operating in New Jersey must register with the Department of Health (DOH) and submit an annual report. The form of the report will be specified further in forthcoming regulations. Among other things, it will include the patient's race and ethnicity, diagnostic codes, evaluation and management codes, and the source of payment for the consult.

10. Will there be any additional rules concerning the Law in the future?

The Law also provides that the state licensing boards shall adopt rules and regulations that are applicable to the healthcare providers under their respective jurisdictions, as may be necessary to implement the provisions of the Law and facilitate the provision of telemedicine and telehealth services. Such rules and regulations shall, at a minimum:

(a) include best practices for the professional engagement in telemedicine and telehealth;

(b) ensure that the services patients receive using telemedicine or telehealth are appropriate, medically necessary, and meet current quality of care standards;

(c) include measures to prevent fraud and abuse in connection with the use of telemedicine and telehealth, including requirements concerning the filing of claims and maintaining appropriate records of services provided; and

(d) provide substantially similar metrics for evaluating quality of care and patient outcomes in connection with services provided using telemedicine and telehealth as currently apply to services provided in-person.

The Law also provides that six months after the effective date, the DOH shall establish "The Telemedicine and Telehealth Review Commission," which shall review the information reported by telemedicine organizations.

Conclusion

The passage of the long-awaited New Jersey Telemedicine Law has provided much needed guidance on the use of telemedicine in the state. However, the laws involving telemedicine are constantly evolving to address new technologies and delivery models. As a result, it is important to keep current on the progress of guidance in this area, including the New Jersey DOH reporting requirements, the applicable professional board rules and regulations, the New Jersey Telemedicine and Telehealth Review Commission activity and federal law.

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